

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method for evaluating the quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including two or more reference data points;

providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least two matching data pairs;

creating a conversion function based on said calibration set;

receiving additional sensor data from the analyte sensor, wherein the step of receiving additional sensor data from the analyte sensor is performed after the step of creating a conversion function;

converting sensor data into calibrated data using said conversion function; and

evaluating the quality of said calibration set using a data association function.

2. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving a data stream that has been algorithmically smoothed.

3. (Original) The method of claim 1, wherein the step of receiving sensor data comprises algorithmically smoothing said data stream.

4. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a substantially continuous glucose sensor.

5. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from an implantable glucose sensor.

6. (Original) The method of claim 1, wherein the step of receiving sensor data comprises receiving sensor data from a subcutaneously implantable glucose sensor.

7. (Original) The method of claim 1, wherein the step of receiving reference data comprises receiving reference data from a self-monitoring blood glucose test.

8. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a cabled connection.

Appl. No. : 10/633,329
Filed : August 1, 2003

9. (Original) The method of claim 1, wherein the step of receiving reference data comprises downloading reference data via a wireless connection.

10. (Original) The method of claim 1, wherein the step of receiving reference data from a reference analyte monitor comprises receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

11. (Canceled)

12. (Original) The method of claim 1, wherein the step of evaluating the quality of said calibration set based on a data association function comprises performing linear least squares regression.

13. (Original) The method of claim 12, wherein the step of evaluating the quality of said calibration set based on a data association function comprises setting a threshold of data association.

14. (Original) The method of claim 13, wherein the step of evaluating the quality of said calibration set based on data association comprises performing linear least squares regression and wherein the step of setting a threshold hold includes an R-value threshold of 0.79.

15. (Original) The method of claim 1, further comprising providing an output to a user interface responsive to the quality of said calibration set.

16. (Original) The method of claim 15, wherein the step of providing an output includes displaying analyte values to a user dependent upon the quality of said calibration.

17. (Currently amended) The method of claim 15, wherein the step of providing an output includes alerting the user dependent upon the quality of said calibration.

18. (Original) The method of claim 15, wherein the step of providing an output includes altering the user interface dependent upon the quality of said calibration.

19. (Original) The method of claim 15, wherein the step of providing an output includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

20. (Currently amended) A system for evaluating the quality of a calibration of an analyte sensor, the system comprising:

means for receiving a data stream from an analyte sensor, a plurality of time-spaced sensor data points;

means for receiving reference data from a reference analyte monitor, including two or more reference data points;

means for providing two or more matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

means for forming a calibration set including at least two matched data ~~pair~~ pairs;

means for creating a conversion function based on said calibration set;

means for prospectively converting sensor data into calibrated data using said conversion function; and

means for evaluating the quality of said calibration set based on a data association function.

21. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data that has been algorithmically smoothed.

22. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for algorithmically smoothing said receiving sensor data.

23. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from substantially continuous glucose sensor.

24. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from an implantable glucose sensor.

25. (Original) The system of claim 20, wherein said means for receiving sensor data comprises means for receiving sensor data from subcutaneously implantable glucose sensor.

26. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for receiving reference data from a self-monitoring blood glucose test.

27. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a cabled connection.

28. (Original) The system of claim 20, wherein said means for receiving reference data comprises means for downloading reference data via a wireless connection.

29. (Original) The system of claim 20, wherein said means for receiving reference data from a reference analyte monitor comprises means for receiving within a receiver internal communication from a reference analyte monitor integral with said receiver.

30. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing one of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

31. (Original) The system of claim 20, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression.

32. (Original) The system of claim 31, wherein said means for evaluating the quality of said calibration set comprises means for setting a threshold of data association.

33. (Original) The system of claim 32, wherein said means for evaluating the quality of said calibration set comprises means for performing linear least squares regression and wherein said means for setting a threshold hold includes an R-value threshold of 0.71.

34. (Original) The system of claim 20, further comprising means for providing an output to a user interface responsive to the quality of said calibration set.

35. (Original) The system of claim 34, wherein said means for providing an output includes means for displaying analyte values to a user dependent upon the quality of said calibration.

36. (Currently amended) The system of claim 34, wherein said means for providing an output includes means for alerting the user dependent upon the quality of said calibration.

37. (Original) The system of claim 34, wherein said means for providing an output includes means for altering the user interface dependent upon the quality of said calibration.

38. (Original) The system of claim 34, wherein said means for providing an output includes at least one of providing color-coded information, trend information, directional information, and fail-safe information.

39. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data receiving module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference data receiving module that receives reference data from a reference analyte monitor, including two or more reference data points;

a data matching module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data;

a calibration set module that forms a calibration set including at least two matched data pairs;

a conversion function module that creates a conversion function using said calibration set;

a sensor data transformation module that prospectively converts sensor data into calibrated data using said conversion function; and

a quality evaluation module that evaluates the quality of said calibration set based on a data association function.

40. (Original) The computer system of claim 39, wherein said sensor data receiving module receives sensor data that has been algorithmically smoothed.

41. (Original) The computer system of claim 39, further comprising a data smoothing module that algorithmically smoothes sensor data received from said sensor data receiving module.

42. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from substantially continuous glucose sensor.

43. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from an implantable glucose sensor.

44. (Original) The computer system of claim 39, wherein said sensor data receiving module is adapted to receive sensor data from subcutaneously implantable glucose sensor.

45. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a self-monitoring blood glucose test.

46. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a cabled connection.

47. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to download reference data via a wireless connection.

Appl. No. : **10/633,329**
Filed : **August 1, 2003**

48. (Original) The computer system of claim 39, wherein said reference data receiving module is adapted to receive reference data from a reference analyte monitor integral with said receiver.

49. (Canceled)

50. (Original) The computer system of claim 39, wherein said quality evaluation module performs linear least squares regression.

51. (Original) The computer system of claim 50, wherein said quality evaluation module sets a threshold for said data association function.

52. (Original) The computer system of claim 51, wherein said quality evaluation module performs linear least squares regression and wherein the threshold of said data association function includes an R-value threshold of at least 0.79.

53. (Original) The computer system of claim 39, further comprising an interface control module that controls the user interface based on the quality of said calibration set.

54. (Original) The computer system of claim 53, wherein said interface control module displays analyte values to a user dependent upon the quality of said calibration set.

55. (Original) The computer system of claim 53, wherein said interface control module alerts the user based upon the quality of said calibration set.

56. (Original) The computer system of claim 53, wherein said interface control module alters the user interface based upon the quality of said calibration set.

57. (Original) The computer system of claim 53, wherein said interface control module provides at least one of color-coded information, trend information, directional information, and fail-safe information.

58. (Currently amended) A method for evaluating the quality of a calibration of an analyte sensor, the method comprising:

receiving a data stream from an analyte sensor, including one or more sensor data points;

receiving reference data from a reference analyte monitor, including two or more reference data points;

providing at least two matched data pairs by matching reference analyte data to substantially time corresponding sensor data;

forming a calibration set including said at least two matching data pairs;
creating a conversion function based on said calibration set;
~~receiving additional sensor data from the analyte sensor;~~
prospectively converting additional sensor data into calibrated data using said
conversion function; and

evaluating the quality of said calibration set based on a data association function
selected from the group consisting of linear regression, non-linear regression, rank
correlation, least mean square fit, mean absolute deviation, and mean absolute relative
difference.

59. (Currently amended) A method for evaluating the quality of a calibration of an
analyte sensor, the method comprising:

~~receiving a data stream~~ analyte sensor data from an analyte sensor, ~~including one~~
~~or more sensor data points;~~

receiving reference data from a reference analyte monitor, ~~including two or more~~
~~reference data points;~~

providing at least two matched data pairs by matching reference analyte data to
substantially time corresponding sensor data;

~~forming a calibration set including said at least two matching data pairs;~~

creating a conversion function based on said at least two matched data pairs
~~calibration set;~~

~~receiving additional sensor data from the analyte sensor;~~

converting sensor data into substantially real-time analyte values ~~calibrated data~~
using said conversion function as sensor data is continuously or intermittently received
from the sensor; and

~~evaluating the quality of said calibration set using a data association function; and~~

providing an output to a user interface responsive to the ~~quality of said calibration~~
set data association of said at least two matched data pairs.

Appl. No. : 10/633,329
Filed : August 1, 2003

60. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module that receives a data stream comprising a plurality of time spaced sensor data points from a substantially continuous analyte sensor;

a reference input module that receives reference data from a reference analyte monitor, including two or more reference data points;

a processor module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data and subsequently forms a calibration set including said two or more matched data pairs; ~~and~~

a conversion function module that creates a conversion function using said calibration set;

a sensor data transformation module that prospectively converts additional sensor data into calibrated data using said conversion function; and

a quality evaluation module that evaluates the quality of said calibration set based on a data association selected from the group consisting of linear regression, non-linear regression, rank correlation, least mean square fit, mean absolute deviation, and mean absolute relative difference.

61. (Currently amended) A computer system for evaluating the quality of a calibration of an analyte sensor, the computer system comprising:

a sensor data module that receives ~~a data stream comprising a plurality of time spaced sensor data points~~ analyte sensor data from a substantially continuous analyte sensor;

a reference input module that receives reference data from a reference analyte monitor, ~~including two or more reference data points~~;

a processor module that forms two or more matched data pairs by matching reference data to substantially time corresponding sensor data ~~and subsequently forms a calibration set including said two or more matched data pairs~~; and

a conversion function module that creates a conversion function using said two or more matched data pairs ~~calibration set~~;

a sensor data transformation module that converts sensor data into substantially real-time analyte values ~~calibrated data~~ using said conversion function as sensor data is continuously or intermittently received from the sensor; and

~~a quality evaluation module that evaluates the quality of said calibration set based on data association; and~~

a fail-safe module that controls the user interface based on the quality data association of said two or more matched data pairs ~~calibration set~~.

62. (Currently amended) A method for evaluating the quality of a calibration of a glucose sensor, the method comprising:

receiving sensor data from a glucose sensor, including one or more sensor data points;

receiving reference data from a reference glucose monitor, including one or more reference data points;

providing one or more matched data pairs by matched reference glucose data to substantially time corresponding sensor data;

forming a calibration set including at least one matched data pair; ~~and~~

evaluating the quality of said calibration set based on data association; and

converting sensor data into calibrated data responsive to the quality of said calibration set.